

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

<h1 style="margin:0;">FSIS DIRECTIVE</h1>	5420.1, Revision 3 Amendment 1	9/7/06
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**HOMELAND SECURITY THREAT CONDITION RESPONSE -
FOOD DEFENSE VERIFICATION PROCEDURES**

NOTE: DO NOT IMPLEMENT THIS DIRECTIVE UNTIL SEPTEMBER 15, 2006.

I. PURPOSE

A. This directive details the emergency Food Defense Verification Procedures that inspection program personnel will follow when the Department of Homeland Security declares a threat condition Yellow, Orange, or Red.

B. This directive also:

- establishes how threat condition declarations will be communicated to field personnel;
- provides specific instructions to field personnel on how to respond to threat condition declarations;
- identifies procedures to effectively address and resolve noted security concerns in order to ensure that food is protected, thereby protecting public health; and
- provides instructions for the Inspector-in-Charge (IIC) when checking to see if an establishment has developed, implemented, tested, assessed, and maintained a food defense plan.

C. If there is an actual terrorist attack on the establishment or surrounding area, the IIC will immediately take measures to make sure inspection program personnel are safe and will notify the District Office (DO). The DO will then notify the appropriate local authorities. In addition, the DO may request the activation of the FSIS Emergency Management Committee (EMC) through the senior executive leadership in the Office of Field Operations (OFO) (see FSIS Directive 5500.2, Non-Routine Incident Response).

DISTRIBUTION: Inspection Offices; T/A Inspectors;
TRA; TSC; Import Offices

OPI: OPPED

II. CANCELLATION

FSIS Directive 5420.1, Revision 3, dated 8/1/06

III. REASON FOR REISSUANCE

FSIS is reissuing this directive in its entirety to revise and consolidate the inspection activities for food defense.

IV. REFERENCES

9 CFR part 300 to end

FSIS Directive 5500.2, Non-Routine Incident Response

V. BACKGROUND

In 2002, the White House Office of Homeland Security established a Homeland Security Advisory System based on color. This System provides a comprehensive and effective means to disseminate information regarding the risk of terrorist acts to Federal, State, and local authorities, and to the American people. A declaration of a Threat Condition Elevated (Yellow) by the Department of Homeland Security indicates there is an elevated risk of terrorist attacks. A declaration of a Threat Condition High (Orange) indicates there is a high risk of terrorist attacks. A declaration of a Threat Condition Severe (Red) reflects a severe risk of terrorist attacks. While the threat may or may not involve the nation's food supply, it is imperative that inspection program personnel take certain actions immediately during such threat conditions to ensure the safety of meat, poultry, and egg products. Given what is required in responding to a credible threat of a terrorist attack, inspection program personnel must clearly understand their roles and what will be required of them to respond properly to that threat.

VI. NOTIFICATION

A. In the event of a declaration of any threat condition:

- Elevated (Yellow), when there is an elevated risk of terrorist attacks,
- High (Orange), when there is a high risk of terrorist attacks, or
- Severe (Red) when there is a severe risk of terrorist attacks,

by the Department of Homeland Security, FSIS' Office of Food Defense and Emergency Response (OFDER) will inform the FSIS Administrator and FSIS Management Council. OFDER will issue an e-mail letter to all employees notifying them of the heightened threat condition.

NOTE: IICs are to make sure a copy of the e-mail letter is available to food inspectors.

B. OFDER will communicate the downgrading of a threat condition to the FSIS Administrator and the FSIS Management Council. Upon notification from the OFO senior executive leadership, the DO will notify the IIC when to return to the Performance Based Inspection System (PBIS) scheduled activities or egg products verification

methodology. The IIC will advise the establishment management that procedures at the lower threat condition have resumed.

VII. SPECIFIC THREAT CONDITION ACTIVITIES

The IIC will instruct inspection program personnel in meat, poultry, and egg products establishments to perform the Food Defense Verification Procedures instead of certain other scheduled non-food safety consumer protection procedures, as follows:

NOTE: Inspection program personnel assigned to meat and poultry establishments will continue to perform all food safety activities assigned by PBIS. Inspection program personnel assigned to egg products establishments will continue to perform all food safety activities as required by current regulatory and policy requirements.

A. Threat Condition Elevated (Yellow), High (Orange), or Severe (Red) with no specific threat to the food and agricultural sector.

1. When the threat condition is elevated (Yellow), high (Orange), or severe (Red) with no specific threat to the food and agricultural sector, inspection program personnel in meat and poultry establishments are to randomly perform one of the Food Defense Verification Procedures listed in paragraph IX., Inspection System Procedure (ISP) code 08S14-08S17. Inspection program personnel are to perform Food Defense Verification Procedures daily for the duration of the threat condition. They are to perform this procedure instead of one of the following scheduled 04 procedures: ISP code 04A01, 04A02, 04A03, 04A04, 04B01, 04B02, 04B03, 04B04, or 04C01.

For example, during a threat condition Orange with no specific threat to the food and agricultural sector, if PBIS schedules ISP codes 04A01 and 04B04 for Tuesday, then inspection program personnel may perform 08S14 in place of either 04A01 or 04B04 on Tuesday. If there are no scheduled 04 procedures on a given day, inspection program personnel are to randomly perform one of the ISP codes 08S14-08S17 once, per plant, per day.

2. Inspection program personnel in egg products processing establishments are to randomly perform one of the Food Defense Verification Procedures listed in paragraph IX. of this directive. Inspection program personnel are to perform one verification procedure daily while the threat condition exists and within the established tour of duty after they perform all food safety procedures.

3. Inspection program personnel are to perform and record in PBIS the Food Defense Verification Procedures as UNSCHEDULED procedures within the established tour of duty and after they have performed all scheduled food safety procedures that they can complete that day.

B. Threat Condition High (Orange) with a specific threat to the food and agricultural sector.

1. When the threat condition is high (Orange), with a specific threat to the food and agricultural sector, inspection program personnel in meat and poultry establishments are to randomly perform three of the procedures from the Food Defense Verification Procedures (ISP codes 08S14-08S17 identified in paragraph IX.) per shift

for the duration of the threat condition. They are to perform these procedures instead of the scheduled 04 procedures. If there are no scheduled 04 procedures on a given day, inspection program personnel are to randomly perform three of the ISP codes 08S14-08S17.

2. Inspection program personnel in egg products processing establishments are to randomly perform three of the procedures from the Food Defense Verification Procedures per shift for the duration of the threat condition within their established tour of duty after all food safety procedures are performed. Inspection program personnel are to select any three from the list of procedures.

3. Inspection program personnel are to perform and record in PBIS, the Food Defense Verification Procedures as UNSCHEDULED procedures within the established tour of duty and after they have performed all scheduled food safety procedures that they can complete that day.

C. Threat Condition Severe (Red) with a specific threat to the food and agricultural sector.

1. When the threat condition is severe (Red) with a specific threat to the food and agricultural sector, inspection program personnel in meat and poultry establishments are to perform ALL of the procedures from the Food Defense Verification Procedures (ISP codes 08S14-08S17) per shift for the duration of the threat condition. They are to perform these procedures instead of the scheduled 04 procedures. If there are no scheduled 04 procedures on a given day, inspection program personnel are to perform all of the ISP codes 08S14-08S17.

2. Inspection program personnel in egg products processing establishments are to perform ALL of the Food Defense Verification Procedures listed in paragraph IX. per shift for the duration of the threat condition within the established tour of duty after they have completed all food safety procedures that they can complete that day.

3. The IIC will receive specific instructions from the DO on other measures that they must take based on information received about the specific threat to a product or process. Such measures may include sampling of specific products, if warranted, to protect public health and taking regulatory actions to address product adulteration or insanitary conditions.

4. The DO will deploy inspection program personnel to establishments producing the products named in the threat condition to make sure FSIS has an on-site presence during any type of operational activity.

5. If inspection program personnel are unable to consistently complete ALL Food Defense Verification Procedures along with the food safety procedures within their normal tour of duty, they are to contact the Frontline Supervisor for guidance regarding which food safety procedures they are to perform, or whether the DO will approve overtime. Inspection program personnel are to perform and record in PBIS the Food Defense Verification procedure as UNSCHEDULED.

D. As an added step that could occur at any risk level, the DO will notify the IIC at specific high-risk establishments when FSIS has identified a specific threat. The DO will instruct the IIC to conduct Food Defense Verification Procedures and to modify the PBIS' scheduled activities or egg products verification methodology, as set forth in paragraph VII of this directive, for the specified threat condition. The IIC will notify the establishment management of the threat condition and of the implementation of the Food Defense Verification Procedures.

VIII. FOOD DEFENSE PLAN

A. Establishments should develop a functional food defense plan to set out control measures to prevent intentional adulteration of product. Although not required, FSIS encourages establishments to have a food defense plan. The plan should be developed, written, implemented, assessed, and maintained if it is to be functional. All establishments should be encouraged to operate with a functional food defense plan. The Agency has developed guidelines on the elements of a food defense plan, and they are available on the FSIS web site at http://www.fsis.usda.gov/pdf/Elements_of_a_Food_Defense_Plan.pdf

B. An establishment is not obligated to provide a copy of its written plan to inspection program personnel. If establishments do provide a copy, inspection program personnel may use the plan when performing the food defense verification activities. If the establishment shares its plan, **do not keep or make copies of the written plan**. Inspection program personnel are not to show or share the plan with any outside source because it may contain sensitive security information.

IX. FOOD DEFENSE VERIFICATION PROCEDURES

A. The purposes of the following emergency Food Defense Verification Procedures are to identify and mitigate to the maximum extent possible potential vulnerabilities in the security of an establishment that could lead to deliberate contamination. A potential vulnerability can be any part (node) of the food production system where a measure should be implemented to protect it from deliberate contamination, but such a measure is found or observed to be missing or not in place. Examples of potential vulnerabilities include uncontrolled access to a restricted ingredient area; unrestricted access to a processing room; or unrestricted access to water systems.

B. At a minimum, the IICs will:

1. Water systems – 08S14

(a) observe the security of the plant's water systems, especially well water and ice storage facilities, and water reuse systems; (b) pay special attention to water used to prepare injection solutions and water and ice used in emulsification (for the production of deli meats and hot dogs); and, (c) to a lesser extent, check water used to prepare surfactant, antimicrobial agent sprays, and chill tank recharge.

Suggested Activities:

Determine whether the establishment:

- controls access to private wells;
- appropriately secures potable water lines or storage tanks; and
- appropriately secures ice storage facilities.

2. Processing/Manufacturing – 08S15

(a) observe production processes (i.e., raw product handling, processing, and packaging of final product) where exposed products are being handled for indications of attempts to introduce contaminants into the product; (b) observe, in particular, operations where the establishment mixes bulk products (i.e., process monitoring by establishment personnel at balance tanks, grinding/emulsification of meat and poultry products, solution injection in preparation areas, and liquid egg product tanker loading areas); and, (c) observe whether the plant has procedures in place to prevent deliberate contamination (e.g., camera surveillance, closed systems, or restricted access of personnel to sensitive production areas).

Suggested Activities:

- Check a production process (e.g., ground beef production area, egg products breaking room) for evidence of possible intentional product contamination.
- Verify the calibration of equipment.
- Check to determine if the plant has implemented a system to restrict access to sensitive processing areas where bulk products are mixed or processed (e.g., camera surveillance, color-coded uniforms, identification badges, and sign-out sheets).

3. Storage Areas – 08S16

(a) observe products in cold and dry storage areas for evidence of tampering; (b) pay special attention to bulk product ingredients that will undergo mixing, such as combo bins of meat trim and poultry parts used for grinding or emulsification; (c) check dry ingredients, including spices, breading materials, and those used in injection solution preparations, for indication of tampering; (d) observe the use and storage of any hazardous materials in the establishment; (e) verify whether entry into such storage areas is controlled and that usage logs are maintained and current; (f) pay special attention to cleaning materials, particularly those used in clean-in-place systems; (g) pay special attention to areas where bulk products are mixed (e.g., storage silos); and, (h) verify the control of laboratory reagents and cultures.

Suggested Activities:

Verify that the establishment has developed and implemented:

- access control procedures to dry ingredient areas;
- access control procedures to raw product storage areas;
- access control procedures to finished product storage areas;
- control procedures for access and use of hazardous chemicals; and
- procedures to check all products in storage for evidence of tampering.

4. Shipping and Receiving – 08S17

(a) observe loading dock areas and vehicular traffic in and out of the establishment; (b) report immediately all unattended deliveries on loading docks and unmarked vehicles parked on the premises to establishment management; (c) verify that the establishment secures, when possible, dry and cold products stored in on-site trailers and parks trailers in a restricted access area of the facility; (d) verify that the facility security staff routinely checks the trailers' physical integrity (e.g., locks, seals, and general condition); and, (e) pay special attention to deliveries of liquid egg products to storage silos, of combo bins of meat trim, and of dry ingredients.

Suggested Activities:

- Check to determine whether the plant has procedures in place to restrict or control access to the loading dock area and verify that the plant has implemented these access control procedures.
- Observe incoming raw materials to verify that the establishment checks deliveries against shipping documents. Pay special attention to tanker trucks and totes of liquid egg products, dry ingredients, combo bins of fresh meat trim or poultry parts, and boxes of frozen trim that the establishment will ship for further processing.

X. DOCUMENTATION

Inspection program personnel are to record the performance of the ISP procedures listed in paragraph IX. and document findings in the following manner:

A. Meat and Poultry

1. When inspection program personnel perform an 08S procedure and do not find a food defense vulnerability or concern, they are to record the procedure as performed by recording trend indicator "A."

2. When inspection program personnel perform an 08S procedure, and find that there **is** a food defense vulnerability or food defense concern, but that there is **no**

evidence of product adulteration, they are to record the procedure, as performed, by recording trend indicator “S” and are to:

- a. immediately notify establishment management and discuss the findings;
- b. complete FSIS Form 5420-1, Food Defense Memorandum of Interview;

NOTE: The form can be found in Outlook:\\Public Folders\\All Public Folders\\Agency Issuances\\Forms\\FSIS 5,000 Series.

- c. provide a copy of the form to plant management; and,
- d. send a copy electronically to the district analyst and the IF-OFDER mailbox in Outlook and maintain a copy in the file.

3. When inspection program personnel perform an 08S procedure, and find that there **is** a food defense vulnerability or food defense concern, and that there **is** evidence of product adulteration, they are to record the procedure as performed by recording trend indicator “T” and are to:

- a. immediately notify establishment management and discuss the findings;
- b. complete an NR for the product adulteration and cite the appropriate ISP code and regulations;
- c. complete FSIS Form 5420-1;
- d. provide a copy of the forms to plant management; and,
- e. send a copy electronically to the district analyst and the IF-OFDER mailbox in Outlook and maintain a copy in the file.

B. Egg Products

Inspection program personnel assigned to egg products establishments are to:

- 1. record the performance of these activities in the Remarks section of the “Daily Report of Plant Operations” (PY-203 for liquid egg products and PY-159 for dried egg products);
- 2. complete FSIS Form 5420-1;
- 3. provide a copy of the form to plant management;
- 4. electronically send a copy to the district analyst and the IF-OFDER mailbox in Outlook, or Fax a copy to OFDER at 202-690-5643; and,

5. attach a copy of the form to the "Daily Report of Plant Operations" and maintain it in the file.

C. The establishment is not under any regulatory obligation to respond. After meeting with plant management and completing FSIS Form 5420-1, inspection program personnel do not need to verify how the establishment addressed the situation. Inspection program personnel are to continue the random selection of food defense procedures as instructed in paragraph IX.

D. If inspection program personnel encounter the same potential food defense vulnerability or concern while randomly conducting food defense procedures, they are to meet with the establishment management and complete a second FSIS Form 5420-1 on this vulnerability. Inspection program personnel are to note on the form that this is the second occurrence of this vulnerability. If inspection program personnel, through the random performance of food defense verification procedures, encounter the same potential food defense vulnerability or concern a third time, they are to: (1) meet once again with the establishment management; (2) complete a third FSIS Form 5420-1; and (3) note that it is the third occurrence of this vulnerability. If the establishment expresses no intention to address the vulnerability or concern, inspection program personnel should notify the DO of this situation through the Frontline Supervisor.

E. The DO will consult with OFDER and will instruct inspection program personnel on how to handle the situation.

Direct all questions on this directive through supervisory channels.



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